Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor / Submitter:	Myoscience, Inc 1600 Seaport Blvd North Lobby, Suite 450 Redwood City, CA 94063 (650) 474-2600 (650) 474-2700
Correspondent Contact Information:	Tracey Henry Vice President RAQA, Operations 1600 Seaport Blvd North Lobby, Suite 450 Redwood City, CA 94063 (650) 474-2600 (650) 474-2900
Device Common Name:	Cryogenic surgical device
Device Classification & Code:	Class II, GXH
Device Classification Name:	Cryosurgical unit and accessories (21 CFR 882.4250)
Device Proprietary Name:	Myoscience Cryo-Touch IV

a. Predicate Device Information:

The Cryo-Touch IV is substantially equivalent to the following currently legally marketed devices:

510(k) Number	Product	Sponsor
K102021	Cryo-Touch II	Myoscience, Inc
K120415	Cryo-Touch III	Myoscience, Inc

b. Date Summary Prepared

November 6, 2012

c. Description of Device

The Myoscience Cryo-Touch IV is a portable cryogenic surgical device used to destroy tissue and/or produce lesions in nervous tissue through application of extreme cold to the selected site. The device is based on introduction of a Smart Tip internally cooled by the cryogenic fluid (nitrous oxide, N_2O) to a selected area. The Smart Tip is cooled by the Joule-Thomson Effect and/or Latent Heat of Vaporization. The Cryo-Touch IV may be used in conjunction with a standard off-the-shelf nerve stimulator device in applications where precise nerve location is desired.

Device Design

The device is comprised of four main components:

1. A reusable Handpiece
2. A Charging Dock
3. A single-patient use Smart Tip
4. A Cartridge (Nitrous Oxide)

The Cryo-Touch IV Handpiece is battery powered and provides feedback to the user during device preparation and use. The Handpiece connects to both the Cartridge and to the Smart Tip. The user

activates a treatment cycle through a control on the Handpiece, which starts and stops the treatment. The Handpiece also contains LEDs for providing feedback to the user when the device is ready to use. The Charging Dock stores the Handpiece between uses and provides power for charging the battery.

An assortment of Smart Tips is available for the Cryo-Touch IV. All Smart Tips needles are made of stainless steel and have a closed-end that fully contains the cryogen so that it does not enter the target tissue. The Smart Tip is the only patient contacting component of the Cryo-Touch IV. The user removes the Smart Tip from the sterile packaging and attaches it to the Handpiece.

The Cryo-Touch IV uses a commercially available nitrous oxide cylinder. The Cartridge is filled with pure N_2O.

Device Functionality/Scientific Concepts

The device functionality is based on the user introducing the Smart Tip to the selected treatment area: unwanted tissue or the target nervous tissue. The user then initiates the flow of cryogen by pressing the on/off button. Liquid cryogen flows from the Handpiece into the closed-end Smart Tip. The Smart Tip is cooled by the Joule-Thomson Effect and/or Latent Heat of Vaporization; as the liquid cryogen expands into a gas, the temperature drops around the external surface of the Smart Tip causing the surrounding tissue to freeze. The treatment is completed after a pre-programmed amount of time at which time the user can safely remove the Smart Tip.

d. Intended Use

The Myoscience Cryo-Touch IV is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. The Cryo-Touch IV is not indicated for treatment of central nervous system tissue.

e. Comparison to Predicate Devices

The Myoscience Cryo-Touch IV is substantially equivalent in intended use, technology, design and materials to the above listed legally marketed predicate devices.

f. Summary of Supporting Data

Nonclinical testing: Verification testing was performed on the Cryo-Touch IV device to demonstrate that the product met the design requirements for system performance. These specific tests are listed below.

Test Performed	Result
Temperature reproducibility	PASS, Substantially equivalent to predicate
Mechanical Integrity for System	PASS, Substantially equivalent to predicate
Nitrous Exposure	PASS, Substantially equivalent to predicate
Cryozone Size	PASS, Substantially equivalent to predicate
Needle Integrity	PASS, Substantially equivalent to predicate
Device Durability	PASS, Substantially equivalent to predicate
Sterilization and Shelf Life Testing	PASS, Substantially equivalent to predicate
Electrical Safety Testing	PASS, Substantially equivalent to predicate
Software Testing	PASS, Substantially equivalent to predicate

Test Performed	Result
Safety Testing	PASS, Substantially equivalent to predicate
Biocompatibility Testing	PASS, Substantially equivalent to predicate

This performance testing demonstrated that the device is in compliance with pertinent standards (IEC 60601-1, IEC 60601-1-2, ISO 10993-1, and ISO 11137-1), the product labeling, and is substantially equivalent to the predicates.

Clinical Testing Submitted:	None

g. Conclusion

Myoscience concludes that the Cryo-Touch IV described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2013

Myoscience, Inc.
% Tracey Henry
Vice President RAQA, Operations
1600 Seaport Boulevard
North Lobby, Suite 450
Redwood City, CA94063

Re: K123516
Trade/Device Name: MyoScience Cryo-Touch IV
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: II
Product Code: GXH
Dated: November 06, 2012
Received: November 14, 2012

Dear Tracey Henry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123516

Device Name: MyoScience Cryo-Touch IV

Indications For Use:

The Myoscience Cryo---Touch IV is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. The Cryo--Touch IV is not indicated for treatment of central nervous system tissue.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123516